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| EXAMINER | |
|---|---|
| MI, QIUWEN | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. 10/517,987 | Applicant(s) GREEN ET AL. | |
|---|---|---|---|
| | Examiner Qiuwen Mi | Art Unit 1655 | |

***-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --***

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *02 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) *1-18 and 55-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/18/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicant's election of Group III, claims 19-54, in the reply filed on 10/2/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

### Claims Pending

Claims 1-64 are pending. Claims 1-18, 55-64 are withdrawn. Claims 19-54 are examined on the merits.

### Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: not every inventor has signed.

## Claim Rejections –35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 26-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray (US 6,005,076).

Murray discloses a method for oil seed protein extraction (see the entire document). Murray teaches extracting rapeseed meal with an aqueous food grade salt solution at a pH of about 5-6.8 at a temperature of about 5-35 °C (col 8, lines 30-40); the extracting step is effected for about 10-60 min (col 8, lines 63-66); the crude protein solution was then chilled to 6 °C for 16 h (col 7, lines 5-8); separating the aqueous protein solution from residual oil seed meal; removing fat from the aqueous protein solution by chilling said aqueous protein solution to a temperature below about 15 °C (col 9, lines 21-26); the fat is separated by decanting, centrifugation and /or fine filtration (claim 7); the supernatant was diafiltered (col 7, lines 45-50), and then concentrated by using a selective ultrafiltration membrane with a molecular weight cut-off of 30,000 (col 7, lines 10-15; claim 13) at a temperature of about 20-45 °C (claim 15); increasing the protein concentration of said defatted protein solution while maintaining the ionic strength thereof substantially constant to form a concentrated defatted protein solution (claim 1d); it is preferred to use a volume reduction factor of about 3.0-about 10 (col 4, lines 55-60); the high protein liquid extract was diluted 10 fold in tap water (6 °C) (col 7, lines 19-21), diluting

the concentrated defatted protein solution to cause the formation of discrete protein particles in the aqueous phase (claim 8e, col 9, lines 32-36); settling the protein micelles to form a mass of protein isolate in the form of an amorphous sticky gelatinous, gluten-like protein micellar mass (claim 8f, col 8, lines 52-57); the micellar mass was allowed to settle for 4 h at 3 °C (col 7, lines 50-55); the dry (desolventized) protein micellar mass has a protein content, usually in excess of about 90% protein (calculated as kjeldahl N x 6.25) (col 6, lines 34-38). See Example 2 in particular.

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use all the teaching of Murray in the entirement document although they are not exactly in one embodiment. Since Murray yielded beneficial results in pharmaceutical industry, one of ordinary skill in the art would have been motivated to make the modifications.

Claims 19-36, 38-45, and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray (US 6,005,076) in view of Jones et al (US 4,158,656).

Murray discloses a method for oil seed protein extraction (see the entire document). Murray teaches extracting rapeseed meal with an aqueous food grade salt solution at a pH of about 5-6.8 at a temperature of about 5-35 °C (col 8, lines 30-40); the extracting step is effected for about 10-60 min (col 8, lines 63-66); the crude protein solution was then chilled to 6 °C for 16 h (col 7, lines 5-8); separating the aqueous protein solution from residual oil seed meal; removing fat from the aqueous protein solution by chilling said aqueous protein solution to a temperature below about 15 °C (col 9, lines 21-26); the fat is separated by decanting,

centrifugation and /or fine filtration (claim 7); the supernatant was diafiltered (col 7, lines 45-50), and then concentrated by using a selective ultrafiltration membrane with a molecular weight cut-off of 30,000 (col 7, lines 10-15; claim 13) at a temperature of about 20-45 °C (claim 15); increasing the protein concentration of said defatted protein solution while maintaining the ionic strength thereof substantially constant to form a concentrated defatted protein solution (claim 1d); it is preferred to use a volume reduction factor of about 3.0-about 10 (col 4, lines 55-60); the high protein liquid extract was diluted 10 fold in tap water (6 °C) (col 7, lines 19-21), diluting the concentrated defatted protein solution to cause the formation of discrete protein particles in the aqueous phase (claim 8e, col 9, lines 32-36); settling the protein micelles to form a mass of protein isolate in the form of an amorphous sticky gelatinous, gluten-like protein micellar mass (claim 8f, col 8, lines 52-57); the micellar mass was allowed to settle for 4 h at 3 °C (col 7, lines 50-55); the dry (desolventized) protein micellar mass has a protein content, usually in excess of about 90% protein (calculated as kjeldahl N x 6.25) (col 6, lines 34-38).

Murray does not teach washing canola oil seed meal with an alcohol (ethanol), ratio of canola oil seed meal in solvent, wash till no visible color is recovered, diafilatration solution contains an antioxidant (ascorbic), or any claimed amounts of antioxidant, membrane cut off point.

Jones et al (US 4,158,656) teach a process for producing protein concentrate product from rapeseed (see Abstract). Jones et al indicate that the problem is that the rapeseed contains numerous phenolic compounds which are readily oxidized and polymerized to condensed tannins which yield dark brown-black pigments. These can cause an unattractive coloration and

undesirable flavour in the food into which they are incorporated and, further, these phenolic compounds can be strongly bound to the protein and thereby diminish the nutritive value of the product (col 3, lines 25-33). The glucosinolates contained in rapeseed are hydrolysed by myrosinase under the appropriate conditions to isothiocyanates, nitriles, and oxazolidinethiones some of which are known to cause goiter. Rapeseed also contains a yellow pigment, the color intensity of which is very much enhanced in alkaline environments, and such coloration is highly undesirable in many food products (col 3, lines 38-47). Jones et al further teach that it is known that thioglucodies can be removed from crushed oilseed by aqueous extraction following a myrosinase inactivating water treatment (col 1, lines 15-24). Phenolics in the rapeseed flour are easily oxidized in alkaline and neutral solutions in the presence of oxygen and it is therefore essential that the extractions should be conducted in a non-oxidizing medium. It is preferable that the solution contains an antioxidant, such as sulphur dioxide, or ascorbic acid (col 4, lines 65-67; col 5, lines 1-5). Jones et al also teach contacting seed material (rapeseed, claim 10) with an aqueous lower alkanol solvent solution (such as ethanol etc, claim 6) (at 20-50 °C) (solvent to solid ratios in the order of 4-10:1, col 4, lines 52-57) to thereby selectively extract glucosinolates, phenolic compounds and pigments therefrom at a temperature below 60 °C and under conditions so as to prevent oxidation of said phenolic compound and inhibiting enzymic degradation of glucosinolates; separating the liquid extract phase from a solid residue, drying (desolventized) the solid residue a at temperature below about 60 °C to thereby recover said protein concentration (claim 1). Jones et al further teach that it is known that thioglucodies can be removed from crushed oilseed by aqueous extraction following a myrosinase inactivating water treatment (col 1, lines 15-24).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the antioxidant ascorbic acid in extracting process, wash rapeseeds with ethanol till no visible color is recovered, and inactivating myrosinase in Jones et al (US 4,158,656) due to the teaching in Jones et al as mentioned above.

Since all the inventions yielded beneficial results in pharmaceutical industry, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of antioxidant, and membrane cut off point, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on the crop and amount of insect control that is needed.

Claims 19-36, and 38-45, 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray (US 6,005,076) in view of Jones et al (US 4,158,656), and further in view of Jones et al (US 6,146,449).

Murray discloses a method for oil seed protein extraction (see the entire document). Murray teaches extracting rapeseed meal with an aqueous food grade salt solution at a pH of about 5-6.8 at a temperature of about 5-35 °C (col 8, lines 30-40); the extracting step is effected for about 10-60 min (col 8, lines 63-66); the crude protein solution was then chilled to 6 °C for

16 h (col 7, lines 5-8); separating the aqueous protein solution from residual oil seed meal; removing fat from the aqueous protein solution by chilling said aqueous protein solution to a temperature below about 15 °C (col 9, lines 21-26); the fat is separated by decanting, centrifugation and /or fine filtration (claim 7); the supernatant was diafiltered (col 7, lines 45-50), and then concentrated by using a selective ultrafiltration membrane with a molecular weight cut-off of 30,000 (col 7, lines 10-15; claim 13) at a temperature of about 20-45 °C (claim 15); increasing the protein concentration of said defatted protein solution while maintaining the ionic strength thereof substantially constant to form a concentrated defatted protein solution (claim 1d); it is preferred to use a volume reduction factor of about 3.0-about 10 (col 4, lines 55-60); the high protein liquid extract was diluted 10 fold in tap water (6 °C) (col 7, lines 19-21), diluting the concentrated defatted protein solution to cause the formation of discrete protein particles in the aqueous phase (claim 8e, col 9, lines 32-36); settling the protein micelles to form a mass of protein isolate in the form of an amorphous sticky gelatinous, gluten-like protein micellar mass (claim 8f, col 8, lines 52-57); the micellar mass was allowed to settle for 4 h at 3 °C (col 7, lines 50-55); the dry (desolventized) protein micellar mass has a protein content, usually in excess of about 90% protein (calculated as kjeldahl N x 6.25) (col 6, lines 34-38). See Example 2 in particular.

Murray does not teach washing canola oil seed meal with an alcohol (ethanol), ratio of canola oil seed meal in solvent, wash till no visible color is recovered, diafilatration solution contains an antioxidant (ascorbic), pasteurizating step, or any claimed amounts of antioxidant, membrane cut off point.

Jones et al (US 4,158,656) teach a process for producing protein concentrate product from rapeseed (see Abstract). Jones et al indicate that the problem is that the rapeseed contains numerous phenolic compounds which are readily oxidized and polymerized to condensed tannins which yield dark brown-black pigments. These can cause an unattractive coloration and undesirable flavour in the food into which they are incorporated and, further, these phenolic compounds can be strongly bound to the protein and thereby diminish the nutritive value of the product (col 3, lines 25-33). The glucosinolates contained in rapeseed are hydrolysed by myrosinase under the appropriate conditions to isothiocyanates, nitriles, and oxazolidinethiones some of which are known to cause goiter. Rapeseed also contains a yellow pigment, the color intensity of which is very much enhanced in alkaline environments, and such coloration is highly undesirable in many food products (col 3, lines 38-47). Jones et al further teach that it is known that thioglucodies can be removed from crushed oilseed by aqueous extraction following a myrosinase inactivating water treatment (col 1, lines 15-24). Phenolics in the rapeseed flour are easily oxidized in alkaline and neutral solutions in the presence of oxygen and it is therefore essential that the extractions should be conducted in a non-oxidizing medium. It is preferable that the solution contains an antioxidant, such as sulphur dioxide, or ascorbic acid (col 4, lines 65-67; col 5, lines 1-5). Jones et al also teach contacting seed material (rapeseed, claim 10) with an aqueous lower alkanol solvent solution (such as ethanol etc, claim 6) (at 20-50 °C) (solvent to solid ratios in the order of 4-10:1, col 4, lines 52-57) to thereby selectively extract glucosinolates, phenolic compounds and pigments therefrom at a temperature below 60 °C and under conditions so as to prevent oxidation of said phenolic compound and inhibiting enzymic degradation of

glucosinolates; separating the liquid extract phase from a solid residue, drying (desolventized) the solid residue a at temperature below about 60 °C to thereby recover said protein concentration (claim 1). Jones et al further teach that it is known that thioglucodies can be removed from crushed oilseed by aqueous extraction following a myrosinase inactivating water treatment (col 1, lines 15-24).

Jones et al (US 6,146,449) teach a method for preparing the high protein nutrient from oilseed-based material. Jones et al indicate that after forming the modified oilseed product, it is typically advisable to pasteurize the material to ensure that microbial activity is minimized. The modified oilseed product may be pasteurized, e.g., by raising the internal temperature of the product to about 75 °C, or above and maintaining that temperature for about 10-15 minutes (col 8, lines 42-50).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the antioxidant ascorbic acid in extracting process, wash rapeseeds with ethanol till no visible color is recovered, and inactivating myrosinase in Jones et al (US 4,158,656) due to the teaching in Jones et al as mentioned above.

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to pasteurization step in Jones et al (US 6,146,449) as Jones et al teach that it is typically advisable to pasteurize the material to ensure that microbial activity is minimized.

Since all the inventions yielded beneficial results in pharmaceutical industry, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of antioxidant, and membrane cut off point, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on the crop and amount of insect control that is needed.

Claims 19-36, and 38-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray (US 6,005,076) in view of Jones et al (US 4,158,656), and Jones et al (US 6,146,449), and further in view of Diosady et al (US 6,905,713).

Murray discloses a method for oil seed protein extraction (see the entire document). Murray teaches extracting rapeseed meal with an aqueous food grade salt solution at a pH of about 5-6.8 at a temperature of about 5-35 °C (col 8, lines 30-40); the extracting step is effected for about 10-60 min (col 8, lines 63-66); the crude protein solution was then chilled to 6 °C for 16 h (col 7, lines 5-8); separating the aqueous protein solution from residual oil seed meal; removing fat from the aqueous protein solution by chilling said aqueous protein solution to a temperature below about 15 °C (col 9, lines 21-26); the fat is separated by decanting, centrifugation and /or fine filtration (claim 7); the supernatant was diafiltered (col 7, lines 45-50),

and then concentrated by using a selective ultrafiltration membrane with a molecular weight cut-off of 30,000 (col 7, lines 10-15; claim 13) at a temperature of about 20-45 °C (claim 15); increasing the protein concentration of said defatted protein solution while maintaining the ionic strength thereof substantially constant to form a concentrated defatted protein solution (claim 1d); it is preferred to use a volume reduction factor of about 3.0-about 10 (col 4, lines 55-60); the high protein liquid extract was diluted 10 fold in tap water (6 °C) (col 7, lines 19-21), diluting the concentrated defatted protein solution to cause the formation of discrete protein particles in the aqueous phase (claim 8e, col 9, lines 32-36); settling the protein micelles to form a mass of protein isolate in the form of an amorphous sticky gelatinous, gluten-like protein micellar mass (claim 8f, col 8, lines 52-57); the micellar mass was allowed to settle for 4 h at 3 °C (col 7, lines 50-55); the dry (desolventized) protein micellar mass has a protein content, usually in excess of about 90% protein (calculated as kjeldahl N x 6.25) (col 6, lines 34-38). See Example 2 in particular.

Murray does not teach washing canola oil seed meal with an alcohol (ethanol), ratio of canola oil seed meal in solvent, wash till no visible color is recovered, diafilatration solution contains an antioxidant (ascorbic), pasteurizating step, contacting PVP, or any claimed amounts of antioxidant, membrane cut off point, or PVP.

Jones et al (US 4,158,656) teach a process for producing protein concentrate product from rapeseed (see Abstract). Jones et al indicate that the problem is that the rapeseed contains numerous phenolic compounds which are readily oxidized and polymerized to condensed tannins

which yield dark brown-black pigments. These can cause an unattractive coloration and undesirable flavour in the food into which they are incorporated and, further, these phenolic compounds can be strongly bound to the protein and thereby diminish the nutritive value of the product (col 3, lines 25-33). The glucosinolates contained in rapeseed are hydrolysed by myrosinase under the appropriate conditions to isothiocyanates, nitriles, and oxazolidinethiones some of which are known to cause goiter. Rapeseed also contains a yellow pigment, the color intensity of which is very much enhanced in alkaline environments, and such coloration is highly undesirable in many food products (col 3, lines 38-47). Jones et al further teach that it is known that thioglucodies can be removed from crushed oilseed by aqueous extraction following a myrosinase inactivating water treatment (col 1, lines 15-24). Phenolics in the rapeseed flour are easily oxidized in alkaline and neutral solutions in the presence of oxygen and it is therefore essential that the extractions should be conducted in a non-oxidizing medium. It is preferable that the solution contains an antioxidant, such as sulphur dioxide, or ascorbic acid (col 4, lines 65-67; col 5, lines 1-5). Jones et al also teach contacting seed material (rapeseed, claim 10) with an aqueous lower alkanol solvent solution (such as ethanol etc, claim 6) (at 20-50 °C) (solvent to solid ratios in the order of 4-10:1, col 4, lines 52-57) to thereby selectively extract glucosinolates, phenolic compounds and pigments therefrom at a temperature below 60 °C and under conditions so as to prevent oxidation of said phenolic compound and inhibiting enzymic degradation of glucosinolates; separating the liquid extract phase from a solid residue, drying (desolventized) the solid residue a at temperature below about 60 °C to thereby recover said protein concentration (claim 1). Jones et al further teach that it is known that thioglucodies can be

removed from crushed oilseed by aqueous extraction following a myrosinase inactivating water treatment (col 1, lines 15-24).

Jones et al (US 6,146,449) teach a method for preparing the high protein nutrient from oilseed-based material. Jones et al indicate that after forming the modified oilseed product, it is typically advisable to pasteurize the material to ensure that microbial activity is minimized. The modified oilseed product may be pasteurized, e.g., by raising the internal temperature of the product to about 75 °C, or above and maintaining that temperature for about 10-15 minutes (col 8, lines 42-50).

Diosady et al the production of high-quality protein isolates from defatted meals (see Title). In the process of isolating protein from canola meal, five grams of insoluble PVP was added to treat the solution for an hour, and then separated by filtration (col 23, lines 10-15).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the antioxidant ascorbic acid in extracting process, wash rapeseeds with ethanol till no visible color is recovered, and inactivating myrosinase in Jones et al (US 4,158,656) due to the teaching in Jones et al as mentioned above.

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to pasteurization step in Jones et al (US 6,146,449) as Jones et al teach that it is typically advisable to pasteurize the material to ensure that microbial activity is minimized.

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the PVP in Diosady et al, as evidenced by Field, tannic acid content can be absorbed on PVP, thus the dark brown-black pigments could be removed.

Since all the inventions yielded beneficial results in pharmaceutical industry, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of antioxidant, membrane cut off point, or PVP, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on the crop and amount of insect control that is needed.

Claims 19-45, and 50-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray (US 6,005,076) in view of Jones et al (US 4,158,656), and Jones et al (US 6,146,449), and further in view of Holbrook et al (US 6,132,795).

Murray discloses a method for oil seed protein extraction (see the entire document). Murray teaches extracting rapeseed meal with an aqueous food grade salt solution at a pH of about 5-6.8 at a temperature of about 5-35 °C (col 8, lines 30-40); the extracting step is effected for about 10-60 min (col 8, lines 63-66); the crude protein solution was then chilled to 6 °C for 16 h (col 7, lines 5-8); separating the aqueous protein solution from residual oil seed meal; removing fat from the aqueous protein solution by chilling said aqueous protein solution to a

temperature below about 15 °C (col 9, lines 21-26); the fat is separated by decanting, centrifugation and /or fine filtration (claim 7); the supernatant was diafiltered (col 7, lines 45-50), and then concentrated by using a selective ultrafiltration membrane with a molecular weight cut-off of 30,000 (col 7, lines 10-15; claim 13) at a temperature of about 20-45 °C (claim 15); increasing the protein concentration of said defatted protein solution while maintaining the ionic strength thereof substantially constant to form a concentrated defatted protein solution (claim 1d); it is preferred to use a volume reduction factor of about 3.0-about 10 (col 4, lines 55-60); the high protein liquid extract was diluted 10 fold in tap water (6 °C) (col 7, lines 19-21), diluting the concentrated defatted protein solution to cause the formation of discrete protein particles in the aqueous phase (claim 8e, col 9, lines 32-36); settling the protein micelles to form a mass of protein isolate in the form of an amorphous sticky gelatinous, gluten-like protein micellar mass (claim 8f, col 8, lines 52-57); the micellar mass was allowed to settle for 4 h at 3 °C (col 7, lines 50-55); the dry (desolventized) protein micellar mass has a protein content, usually in excess of about 90% protein (calculated as kjeldahl N x 6.25) (col 6, lines 34-38). See Example 2 in particular.

Murray does not teach washing canola oil seed meal with an alcohol (ethanol), ratio of canola oil seed meal in solvent, wash till no visible color is recovered, diafilatration solution contains an antioxidant (ascorbic), pasteurizating step, extracting protein isolate with alcoholic solution, or any claimed amounts of antioxidant, membrane cut off point.

Jones et al (US 4,158,656) teach a process for producing protein concentrate product from rapeseed (see Abstract). Jones et al indicate that the problem is that the rapeseed contains numerous phenolic compounds which are readily oxidized and polymerized to condensed tannins which yield dark brown-black pigments. These can cause an unattractive coloration and undesirable flavour in the food into which they are incorporated and, further, these phenolic compounds can be strongly bound to the protein and thereby diminish the nutritive value of the product (col 3, lines 25-33). The glucosinolates contained in rapeseed are hydrolysed by myrosinase under the appropriate conditions to isothiocyanates, nitriles, and oxazolidinethiones some of which are known to cause goiter. Rapeseed also contains a yellow pigment, the color intensity of which is very much enhanced in alkaline environments, and such coloration is highly undesirable in many food products (col 3, lines 38-47). Jones et al further teach that it is known that thioglucodies can be removed from crushed oilseed by aqueous extraction following a myrosinase inactivating water treatment (col 1, lines 15-24). Phenolics in the rapeseed flour are easily oxidized in alkaline and neutral solutions in the presence of oxygen and it is therefore essential that the extractions should be conducted in a non-oxidizing medium. It is preferable that the solution contains an antioxidant, such as sulphur dioxide, or ascorbic acid (col 4, lines 65-67; col 5, lines 1-5). Jones et al also teach contacting seed material (rapeseed, claim 10) with an aqueous lower alkanol solvent solution (such as ethanol etc, claim 6) (at 20-50 °C) (solvent to solid ratios in the order of 4-10:1, col 4, lines 52-57) to thereby selectively extract glucosinolates, phenolic compounds and pigments therefrom at a temperature below 60 °C and under conditions so as to prevent oxidation of said phenolic compound and inhibiting enzymic degradation of glucosinolates; separating the liquid extract phase from a solid residue, drying (desolventized)

the solid residue a at temperature below about 60 °C to thereby recover said protein concentration (claim 1). Jones et al further teach that it is known that thioglucodies can be removed from crushed oilseed by aqueous extraction following a myrosinase inactivating water treatment (col 1, lines 15-24).

Jones et al (US 6,146,449) teach a method for preparing the high protein nutrient from oilseed-based material. Jones et al indicate that after forming the modified oilseed product, it is typically advisable to pasteurize the material to ensure that microbial activity is minimized. The modified oilseed product may be pasteurized, e.g., by raising the internal temperature of the product to about 75 °C, or above and maintaining that temperature for about 10-15 minutes (col 8, lines 42-50).

Holbrook et al teach that vegetable protein concentrate or vegetable protein isolate is an alcohol extract or washed material since alcohol extraction provides a protein material especially suitable for use in a food material (col 5, lines 15-20). Holbrook et al also teach that vegetable materials which contain protein and isoflavones include oilseeds such as rapeseed etc (col 8, lines 64-67; col 9, lines 1-5).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the antioxidant ascorbic acid in extracting process, wash rapeseeds with ethanol till no visible color is recovered, and inactivating myrosinase in Jones et al (US 4,158,656) due to the teaching in Jones et al as mentioned above.

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to pasteurization step in Jones et al (US 6,146,449) as Jones et al teach that it is typically advisable to pasteurize the material to ensure that microbial activity is minimized.

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to extract canola protein isolate with aqueous alcoholic solution as Holbrook et al teach that alcohol extraction provides a protein material especially suitable for use in a food material.

Since all the inventions yielded beneficial results in pharmaceutical industry, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of antioxidant, and membrane cut off point, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on the crop and amount of insect control that is needed.

Claims 19-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murray (US 6,005,076) in view of Jones et al (US 4,158,656), and Jones et al (US 6,146,449), and further in view of Diosady et al (US 6,905,713), and Holbrook et al (US 6,132,795).

Murray discloses a method for oil seed protein extraction (see the entire document). Murray teaches extracting rapeseed meal with an aqueous food grade salt solution at a pH of about 5-6.8 at a temperature of about 5-35 °C (col 8, lines 30-40); the extracting step is effected for about 10-60 min (col 8, lines 63-66); the crude protein solution was then chilled to 6 °C for 16 h (col 7, lines 5-8); separating the aqueous protein solution from residual oil seed meal; removing fat from the aqueous protein solution by chilling said aqueous protein solution to a temperature below about 15 °C (col 9, lines 21-26); the fat is separated by decanting, centrifugation and /or fine filtration (claim 7); the supernatant was diafiltered (col 7, lines 45-50), and then concentrated by using a selective ultrafiltration membrane with a molecular weight cut-off of 30,000 (col 7, lines 10-15; claim 13) at a temperature of about 20-45 °C (claim 15); increasing the protein concentration of said defatted protein solution while maintaining the ionic strength thereof substantially constant to form a concentrated defatted protein solution (claim 1d); it is preferred to use a volume reduction factor of about 3.0-about 10 (col 4, lines 55-60); the high protein liquid extract was diluted 10 fold in tap water (6 °C) (col 7, lines 19-21), diluting the concentrated defatted protein solution to cause the formation of discrete protein particles in the aqueous phase (claim 8e, col 9, lines 32-36); settling the protein micelles to form a mass of protein isolate in the form of an amorphous sticky gelatinous, gluten-like protein micellar mass (claim 8f, col 8, lines 52-57); the micellar mass was allowed to settle for 4 h at 3 °C (col 7, lines 50-55); the dry (desolventized) protein micellar mass has a protein content, usually in excess of about 90% protein (calculated as kjeldahl N x 6.25) (col 6, lines 34-38). See Example 2 in particular.

Murray does not teach washing canola oil seed meal with an alcohol (ethanol), ratio of canola oil seed meal in solvent, wash till no visible color is recovered, diafilatration solution contains an antioxidant (ascorbic), pasteurizating step, or any claimed amounts of antioxidant, membrane cut off point, or PVP.

Jones et al (US 4,158,656) teach a process for producing protein concentrate product from rapeseed (see Abstract). Jones et al indicate that the problem is that the rapeseed contains numerous phenolic compounds which are readily oxidized and polymerized to condensed tannins which yield dark brown-black pigments. These can cause an unattractive coloration and undesirable flavour in the food into which they are incorporated and, further, these phenolic compounds can be strongly bound to the protein and thereby diminish the nutritive value of the product (col 3, lines 25-33). The glucosinolates contained in rapeseed are hydrolysed by myrosinase under the appropriate conditions to isothiocyanates, nitriles, and oxazolidinethiones some of which are known to cause goiter. Rapeseed also contains a yellow pigment, the color intensity of which is very much enhanced in alkaline environments, and such coloration is highly undesirable in many food products (col 3, lines 38-47). Jones et al further teach that it is known that thioglucodies can be removed from crushed oilseed by aqueous extraction following a myrosinase inactivating water treatment (col 1, lines 15-24). Phenolics in the rapeseed flour are easily oxidized in alkaline and neutral solutions in the presence of oxygen and it is therefore essential that the extractions should be conducted in a non-oxidizing medium. It is preferable that the solution contains an antioxidant, such as sulphur dioxide, or ascorbic acid (col 4, lines 65-67; col 5, lines 1-5). Jones et al also teach contacting seed material (rapeseed, claim 10) with an

aqueous lower alkanol solvent solution (such as ethanol etc, claim 6) (at 20-50 °C) (solvent to solid ratios in the order of 4-10:1, col 4, lines 52-57) to thereby selectively extract glucosinolates, phenolic compounds and pigments therefrom at a temperature below 60 °C and under conditions so as to prevent oxidation of said phenolic compound and inhibiting enzymic degradation of glucosinolates; separating the liquid extract phase from a solid residue, drying (desolventized) the solid residue a at temperature below about 60 °C to thereby recover said protein concentration (claim 1). Jones et al further teach that it is known that thioglucodies can be removed from crushed oilseed by aqueous extraction following a myrosinase inactivating water treatment (col 1, lines 15-24).

Jones et al (US 6,146,449) teach a method for preparing the high protein nutrient from oilseed-based material. Jones et al indicate that after forming the modified oilseed product, it is typically advisable to pasteurize the material to ensure that microbial activity is minimized. The modified oilseed product may be pasteurized, e.g., by raising the internal temperature of the product to about 75 °C, or above and maintaining that temperature for about 10-15 minutes (col 8, lines 42-50).

Diosady et al the production of high-quality protein isolates from defatted meals (see Title). In the process of isolating protein from canola meal, five grams of insoluble PVP was added to treat the solution for an hour, and then separated by filtration (col 23, lines 10-15).

Holbrook et al teach that vegetable protein concentrate or vegetable protein isolate is an alcohol extract or washed material since alcohol extraction provides a protein material especially suitable for use in a food material (col 5, lines 15-20). Holbrook et al also teach that vegetable materials which contain protein and isoflavones include oilseeds such as rapeseed etc (col 8, lines 64-67; col 9, lines 1-5).

It would have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the antioxidant ascorbic acid in extracting process, wash rapeseeds with ethanol till no visible color is recovered, and inactivating myrosinase in Jones et al (US 4,158,656) due to the teaching in Jones et al as mentioned above.

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to pasteurization step in Jones et al (US 6,146,449) as Jones et al teach that it is typically advisable to pasteurize the material to ensure that microbial activity is minimized.

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to use the PVP in Diosady et al, as evidenced by Field, tannic acid content can be absorbed on PVP, thus the dark brown-black pigments could be removed.

It would also have been *prima facie* obvious for one of ordinary skill in the art at the time the invention was made to extract canola protein isolate with aqueous alcoholic solution as Holbrook et al teach that alcohol extraction provides a protein material especially suitable for use in a food material.

Since all the inventions yielded beneficial results in pharmaceutical industry, one of ordinary skill in the art would have been motivated to make the modifications. Regarding the limitation to the amount of antioxidant, membrane cut off point, or PVP, the result-effective adjustment in conventional working parameters is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan, which is dependent on the crop and amount of insect control that is needed.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is *prima facie* obvious over the references, especially in the absence of evidence to the contrary.

*This reference is cited merely to relay an intrinsic property and is not used in the basis for rejection *per se.*

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**Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Qiuwen Mi

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